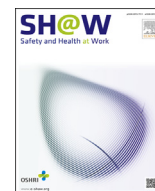


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Original Article

Biorisk Assessment of Medical Diagnostic Laboratories in Nigeria

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ABSTRACT

Background: The aim of this study was to assess public and private medical diagnostic laboratories in Nigeria for the presence of biosafety equipment, devices, and measures.

Methods: A total of 80 diagnostic laboratories in biosafety level 3 were assessed for the presence of biosafety equipment, devices, and compliance rate with biosafety practices. A detailed questionnaire and checklist was used to obtain the relevant information from enlisted laboratories.

Results: The results showed the presence of an isolated unit for microbiological work, leak-proof working benches, self-closing doors, emergency exits, fire extinguisher(s), autoclaves, and hand washing sinks in 21.3%, 71.3%, 15.0%, 1.3%, 11.3%, 82.5%, and 67.5%, respectively, of all laboratories surveyed. It was observed that public diagnostic laboratories were significantly more likely to have an isolated unit for microbiological work ($p = 0.001$), hand washing sink ($p = 0.003$), and an autoclave ($p \leq 0.001$) than private ones. Routine use of hand gloves, biosafety cabinet, and a first aid box was observed in 35.0%, 20.0%, and 2.5%, respectively, of all laboratories examined. Written standard operating procedures, biosafety manuals, and biohazard signs on door entrances were observed in 6.3%, 1.3%, and 3.8%, respectively, of all audited laboratories. No biosafety officer(s) or records of previous spills, or injuries and accidents, were observed in all diagnostic laboratories studied.

Conclusion: In all laboratories (public and private) surveyed, marked deficiencies were observed in the area of administrative control responsible for implementing biosafety. Increased emphasis on provision of biosafety devices and compliance with standard codes of practices issued by relevant authorities is strongly advocated.

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1. Introduction

All procedures in the diagnostic medical laboratories are not without associated risks. Laboratory personnel handling clinical samples containing highly infectious agents are at a high risk of contracting laboratory-acquired infection. This risk is particularly high for those working in microbiological laboratories [1,2]. Injuries through infected needles and sharp cutting instruments encountered in diagnostic procedures represent potential sources of laboratory-acquired infections. These infections could result in

poor performance of laboratory personnel and, in extreme cases, loss of infected laboratory staff [2]. Laboratory-acquired infections involving contagious diseases have also demonstrated the potential to spread beyond the laboratory into the general community at large [3].

Studies indicate that most hospitals in developing countries, especially those in Africa, have rudimentary and highly compromised infection control programs owing to the lack of awareness of the problem; lack of personnel trained in infection control practices; inadequate and aging infrastructure; irregular supply of

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gloves, masks, and disinfectants; and poor laboratory backup [4]. The situation in private and public clinical diagnostic laboratories that constitute an integral part of most hospitals in Nigeria is unlikely to be any different.

Laboratory biosafety has been described as the containment principles, technologies, and practices implemented to prevent unintentional exposure to pathogens and toxins or their accidental release [5]. Several laboratory-associated infections have occurred in different parts of the world involving both known and previously unknown agents [3]. Use of protective clothing and safety gadgets alone may not guarantee the safety of the laboratory personnel. There should always be a combination of policies and systems to protect the laboratory workers from the risk of laboratory-associated infections. Improper containment and poor disposal of biomedical wastes is a potential source of infection to health care workers, patients, and the community at large [6]. Reports have also associated good room ventilation with reduced risks of acquiring airborne infection in hospital settings [7].

Hospitals and diagnostic laboratories are at the forefront of disease detection in Nigeria. They are expected to have the capacity to handle and detect known or unknown (novel) biological agents. Although diagnostic laboratories are important in the fight against infectious diseases, laboratory workers are generally faced with many occupational risks that may jeopardize their health [8]. Evidence exists that compliance with universal safety precautions reduces the risk of infections and protects health care practitioners [9]. Regular monitoring and assessment of diagnostic laboratories for the presence of biosafety devices and compliance rate with standard biosafety measures therefore will not only promote a safer working environment, but could also impact greatly on maintaining qualitative laboratory service delivery. In Nigeria, there is currently no legislative guideline for enforcing biosafety in clinical laboratories. At present, very few reports exist on biorisk assessment of clinical diagnostic laboratories in the country. Against this background, the aim of this study was to assess public and private laboratories in Nigeria for the presence of biosafety equipment and compliance rate with safety measures.

2. Materials and methods

2.1. Study centers

A total of 80 diagnostic laboratories were used for this study. The focus was on diagnostic laboratories that carry out microbiological work with any of the microorganisms of biosafety level 3. The 80 laboratories consisted of four public laboratories in tertiary health care facilities, 14 public laboratories in secondary health care facilities, and 13 public laboratories in primary health care facilities. Others included two private laboratories in tertiary health care facilities, 22 private laboratories in secondary health care facilities, and 25 privately owned laboratories in nonhospital settings. A

detailed questionnaire and checklist was used to obtain relevant information from the heads and/or owner of each laboratory. Study approval was obtained from ethical committees of all public and private health care facility where the laboratories were situated. Approval was sought and obtained from owners and/or heads of private laboratories in nonhospital settings. Facility confidentiality was strictly maintained.

2.2. Statistical analysis

The data obtained were analyzed using Fisher's exact test and odds ratio (OR) analysis applying the statistical software INSTAT® (GraphPad Software, Inc., La Jolla, CA, USA). Statistical significance was set at $p < 0.05$.

3. Results

3.1. Biosafety engineered devices

Based on the results, an isolated unit for microbiological work, leak-proof working benches, self-closing doors, emergency exits, and hand washing sinks were observed in 21.3%, 71.3%, 15.0%, 1.3%, and 67.5%, respectively, of all laboratories surveyed. A fire extinguisher and an autoclave was observed in 11.3% and 82.5%, respectively, of the audited laboratories. Compared with private diagnostic laboratories, public diagnostic laboratories were significantly more likely to have an isolated unit for microbiological work ($p = 0.001$), hand washing sinks ($p = 0.003$), and an autoclave ($p \leq 0.001$) (Table 1). A statistically significant difference was observed between public and private diagnostic laboratories with respect to isolated units for microbiological work in secondary health care facilities ($p = 0.007$), whereas that for hand washing sink was observed only in primary health care facilities ($p = 0.019$). Although the presence of leak-proof working benches did not differ significantly between public and private laboratories generally ($p = 0.448$), public primary health-care laboratories were more likely to have leak-proof working benches than their private counterparts [OR = 20.407; 95% confidence interval (CI), 1.079–385.86; $p = 0.006$]. Secondary laboratories in the public sector were significantly more likely to have an autoclave than those in the private sector (OR = 14.032; 95% CI, 0.733–208.54; $p = 0.028$) (Table 2).

3.2. Personal protective devices

A biosafety cabinet and a first aid box was observed in 20.0% and 2.5%, respectively, of all laboratories examined. Routine use of hand gloves was recorded in 35.0% of laboratories. The routine use of hand gloves and presence of biosafety cabinets was significantly associated with public diagnostic laboratories ($p < 0.05$) (Table 3). Comparison of different tiers of laboratories showed that public

Table 1
Biosafety engineered devices in diagnostic laboratories

Variables	Public laboratories		Private laboratories		OR	95% CI	p
	N	No. present (%)	N	No. present (%)			
Isolated laboratory unit	31	13 (41.9)	49	4 (8.2)	8.125	2.334–28.279	0.001
Leak-proof working benches	31	24 (77.4)	49	33 (67.3)	1.662	0.592–4.668	0.448
Self-closing doors	31	7 (22.6)	49	5 (10.2)	2.567	0.735–8.968	0.198
Emergency exit	31	1 (3.2)	49	0 (0.0)	4.369	0.192–123.40	0.388
Hand washing sink	31	27 (87.1)	49	27 (55.1)	5.500	1.610–18.110	0.003
Fire extinguisher	31	6 (19.4)	49	3 (6.1)	3.680	0.846–15.995	0.082
Autoclave	31	31 (100.0)	49	35 (71.4)	25.732	1.473–449.5	<0.001

CI, confidence interval; N, number of laboratories; OR, odds ratio.

Table 2
Comparison of different tiers of public and private laboratories for biosafety engineered devices

Characteristics	Class of laboratory	Public laboratories		Private laboratories		OR	95% CI	p
		N ₁	No. with device (%)	N ₂	No. with device (%)			
Isolated micro lab	Tertiary	4	4 (100.0)	2	2 (100.0)	—	—	—
	Secondary	14	8 (57.1)	22	1 (4.5)	28.000	2.896–270.60	0.007
	Primary	13	1 (7.7)	25	1 (4.0)	2.000	0.115–34.84	1.000
Leak-proof benches	Tertiary	4	4 (100.0)	2	2 (100.0)	—	—	—
	Secondary	14	14 (100.0)	22	13 (59.1)	20.407	1.079–385.86	0.006
	Primary	13	6 (46.2)	25	18 (72.0)	3.000	0.740–12.130	0.163
Self-closing doors	Tertiary	4	2 (50.0)	2	0 (0.0)	5.000	0.149–166.73	0.467
	Secondary	14	5 (35.7)	22	4 (18.2)	2.500	0.530–11.656	0.267
	Primary	13	0 (0.0)	25	1 (4.0)	0.604	0.023–15.911	1.000
Emergency exit	Tertiary	4	1 (25.0)	2	0 (0.0)	2.143	0.059–77.605	1.000
	Secondary	14	0 (0.0)	22	0 (0.0)	—	—	—
	Primary	13	0 (0.0)	25	0 (0.0)	—	—	—
Hand washing sink	Tertiary	4	4 (100.0)	2	2 (100.0)	—	—	—
	Secondary	14	14 (100.0)	22	18 (81.8)	2.189	0.0987–48.536	1.000
	Primary	13	9 (69.2)	25	7 (28.0)	5.786	1.335–25.074	0.019
Autoclave	Tertiary	4	4 (100.0)	2	2 (100.0)	—	—	—
	Secondary	14	14 (100.0)	22	15 (68.2)	14.032	0.733–208.54	0.028
	Primary	13	13 (100.0)	25	18 (72.0)	10.940	0.5740–208.75	0.072
Fire extinguisher	Tertiary	4	2 (50.0)	2	1 (50.0)	—	—	—
	Secondary	14	4 (28.6)	22	1 (4.5)	8.400	0.827–85.276	0.064
	Primary	13	0 (0.0)	25	1 (4.0)	0.605	0.023–15.911	1.000

CI, confidence interval; micro lab, microbiology laboratory; N₁, number of public laboratories; N₂, number of private laboratories; OR, odds ratio.

secondary laboratories were significantly more likely to have a biosafety cabinet and routinely use hand gloves than secondary laboratories in the private sector ($p < 0.05$) (Table 4).

3.3. Administrative control of biosafety

A written set of standard operating procedures (SOPs) was found in five (6.3%) of all diagnostic laboratories surveyed. The presence of a biosafety manual and a biohazard sign on a laboratory doorpost was observed in one (1.3%) and three (3.8%) of all laboratories studied, respectively. Hepatitis B virus (HBV) immunization policy was recorded in eight (10%) laboratories. No biosafety officers or records of previous spills, injuries, accidents, and infections that occurred in the laboratory were observed in all diagnostic laboratories (Table 5). Comparison of different tiers of public and private laboratories did not show any significant difference in relation with administrative control of biosafety ($p > 0.05$) (Table 6).

4. Discussion

The safety of the laboratory personnel working in diagnostic laboratories is of prime importance in ensuring the continued delivery of prompt and quality laboratory services. The environment in which laboratory testing is performed should be conducive for efficient operations and must not compromise the safety of the staff or the quality of the services rendered [10]. Against this

background, this study aimed at assessing public and private diagnostic laboratories for the presence of biosafety devices, equipment, and compliance rate with biosafety practices in Nigeria.

The presence of an isolated microbiological laboratory and a hand washing sink was observed in 21.3% and 67.5%, respectively, of laboratories surveyed. The medical microbiology laboratory was observed to be isolated and in an area of low traffic in all public and private tertiary health care institutions surveyed. This was not the case in public secondary and primary laboratories. The worst situation was observed in private primary laboratories, where more than 95% of them were situated in buildings with heavy human traffic and where other nonmedical commercial activities took place daily. Diagnostic laboratories in secondary public health care institutions were significantly more likely ($p = 0.007$) to be located in an isolated and restricted area than those found in secondary private health care facilities. Generally, a public diagnostic laboratory was 2–28 times more likely to be in a separate and restricted unit than one in the private sector. Hand washing sink was observed in 87.1% and 55.1% of public and private laboratories, respectively. Public diagnostic laboratories were significantly more likely ($p = 0.003$) to have a washing sink in place than private laboratories. The poorest use of hand washing sink was observed in private primary laboratories. A significant association was found to exist between nonpresence of hand washing sinks and private primary laboratories ($p = 0.019$). In more than 70% of primary private laboratories, hand washing after work was done by pouring water from a cup onto a person's hands and collecting used water in a bowl, which was discarded at the end of the day. The effluent from such procedures was not channeled into a safe and enclosed receptacle outside of the laboratory. Accidental spillage of such wastewater could place laboratory workers at high risk of acquiring infection.

Self-closing entrance doors and an emergency exit channel were observed in twelve (15.0%) and one (1.25%) of all laboratories surveyed, respectively. The marked absence of self-closing entrance doors observed in this study represents a high risk of exporting infectious materials to the unsuspecting nonlaboratory staff and the surrounding environment in general. Laboratory personnel working in a facility with no emergency exit channel may have little or no alternative route of escape in the event of fire outbreaks or

Table 3
Personal protective devices in diagnostic laboratories

Variables	Public laboratories		Private laboratories		OR	95% CI	p
	N	No. present (%)	N	No. present (%)			
Biosafety cabinet	31	14 (45.2)	49	2 (4.1)	19.353	3.977–94.186	<0.001
Routine hand glove use	31	18 (54.1)	49	10 (20.4)	5.400	1.994–14.60	0.001
First aid box	31	2 (6.5)	49	0 (0.0)	8.390	0.3890–180.94	0.147

CI, confidence interval; N, number of laboratories; OR, odds ratio.

Table 4

Comparison of different tiers of public and private laboratories for personal protective devices

Characteristics	Class of laboratory	Public laboratories		Private laboratories		OR	95% CI	p
		N ₁	No. with device (%)	N ₂	No. with device (%)			
Biosafety cabinet	Tertiary	4	4 (100.0)	2	1 (50.0)	9.000	0.233–362.81	0.333
	Secondary	14	10 (71.4)	22	1 (4.5)	52.500	5.171–532.98	<0.001
	Primary	13	0 (0.0)	25	0 (0.0)	—	—	—
Routine hand glove use	Tertiary	4	4 (100.0)	2	1 (50.0)	9.000	0.233–362.81	0.333
	Secondary	14	10 (71.4)	22	3 (13.6)	15.833	2.946–85.111	0.001
	Primary	13	4 (30.7)	25	6 (24.0)	1.407	0.316–6.267	0.709
First aid box	Tertiary	4	2 (50.0)	2	0 (0.0)	5.000	0.149–166.73	0.467
	Secondary	14	0 (0.0)	22	0 (0.0)	—	—	—
	Primary	13	0 (0.0)	25	0 (0.0)	—	—	—

CI, confidence interval; N₁, number of public laboratories; N₂, number of private laboratories; OR, odds ratio.

other life-threatening emergencies. Although more public diagnostic laboratories were equipped with self-closing doors (22.6%) and emergency exit units (3.2%), the difference was not statistically significant. In Nigeria, it is common practice for private laboratory owners to rent any store or apartment without considering laboratory design just as most laboratories are designed and built without input from laboratory professionals in public health care facilities. This may explain the finding in this study. An autoclave was observed in all public laboratories. All private laboratories in tertiary health care setting also had at least an autoclave. The same could not be said of secondary and primary private laboratories, where the absence of an autoclave was observed in 32.0% and 28.0% of surveyed laboratories, respectively. This was shocking as these laboratories admitted to routinely carrying out culture of clinical samples. The autoclave comes in handy for proper sterilization of contaminated culture and materials before removal from the laboratory. Failure to do this routinely and properly may not only compromise the quality of culture results, but could also expose laboratory personnel to infectious agents from improperly sterilized materials. Generally, public laboratories were observed to be 1–400 times more likely to have an autoclave than private laboratories. A fire extinguisher was observed in 11.3% of laboratories surveyed. This is in contrast to 73.9% reported in an earlier study [11]. Of all laboratories examined, working benches were least covered with leak-proof materials in those within public primary health care centers. This was least surprising as reports shows that most primary health care centers in Nigeria are in a state of disrepair with equipment and infrastructure being either absent or obsolete [12]. Increased emphasis on structural design of laboratories to meet with international biosafety guidelines in Nigeria is advocated.

Furthermore, a safety cabinet was observed in 16 (20.0%) of all audited laboratories. This differs from a rate of 5.8% reported in a

previous study [13]. No biosafety cabinet was found in all public and private primary laboratories. However, public laboratories were significantly more likely ($p \leq 0.0001$) to have a biosafety cabinet than private laboratories. An attempt to compare different tiers of laboratories also revealed a similar difference between public secondary and private secondary laboratories. Culture of specimen, for example, sputum that contains highly contagious agents such as *Mycobacterium tuberculosis*, in laboratories without safety cabinets represents a serious threat to the health of laboratory workers.

Routine use of hand gloves in handling clinical specimens was recorded in 35% of all laboratories in this study. The highest use of hand gloves was observed in public laboratories in tertiary health care facilities. This was found to reduce steadily from public secondary to public primary laboratories. No significant difference was observed in issues relating to hand glove use between the different tiers of laboratories except those in the secondary category with public laboratories recording a higher rate of use. Generally, however, hand gloves were 2–15 times more likely to be used in public diagnostic laboratories than in private ones. Correct and consistent use of hand gloves by health workers reduces the risk of acquiring occupational related diseases [14]. Renewed emphasis by laboratory managers on routine use of hand gloves especially among health workers in private laboratories is necessary.

The incidence of infection with HBV has declined in health care workers in recent years largely because of widespread immunization with hepatitis B vaccine [15]. In this study, only eight (10%) laboratories had an HBV vaccination program for all laboratory workers. Findings from a Nigerian study carried out on laboratory health workers in two teaching hospitals in Nigeria reveals that more than 90% of them were not immunized against HBV [16]. This trend, and indeed the poor policy of HBV vaccination program observed in this study, puts laboratory workers at increased risk of acquiring occupational related HBV infection from handling of blood samples.

A biosafety manual was found in one (3.2%) of all laboratories examined. This is a far cry from the 56.5% previously reported in an Indian study [13]. The only manual observed in this study was found in a laboratory situated in a public tertiary health care facility. No statistical difference was observed in the presence of biosafety manual in private and public laboratories. The World Health Organization over the years has revised the laboratory biosafety manual with new information on risk assessment, safe use of recombinant DNA technology, and transport of infectious materials [17]. This marked absence of laboratory biosafety manual in laboratories surveyed paints a worrisome picture of the biosafety consciousness level of laboratory heads and managers and staff of laboratories examined. This is further amplified by the complete absence of record of previous spills and accidents in all laboratories examined. The presence of record of spills and accidents in diagnostic laboratories could aid health managers and planners to identify safety needs, articulate new safety measures, and influence decision

Table 5

Administrative control of safety in diagnostic laboratories

Variables	Public laboratories		Private laboratories		OR	95% CI	p
	N	No. present (%)	N	No. present (%)			
Written SOPs	31	5 (16.1)	49	0 (0.0)	20.550	1.093–386.33	0.007
HBV vaccination policy	31	6 (19.4)	49	2 (4.1)	5.640	1.059–30.040	0.082
Record spills/accidents	31	0 (0.0)	49	0 (0.0)	—	—	—
Biosafety officer	31	0 (0.0)	49	0 (0.0)	—	—	—
Biosafety manual	31	1 (3.2)	49	0 (0.0)	4.870	0.192–123.46	0.388
Biohazard sign	31	3 (9.7)	49	0 (0.0)	12.158	0.606–244.05	0.055

CI, confidence interval; HBV, Hepatitis B virus; N, number of laboratories; OR, odds ratio; SOPs, standard operating procedures.

Table 6

Comparison of different tiers of public and private laboratories for administrative control of safety

Characteristics	Class of laboratory	Public laboratories		Private laboratories		OR	95% CI	p
		N ₁	No. with device (%)	N ₂	No. with device (%)			
Written SOP	Tertiary	4	2 (50)	2	0 (0.0)	5.000	0.1449–186.73	0.466
	Secondary	14	3 (21.4)	22	0 (0.0)	13.696	0.650–288.59	0.051
	Primary	13	0 (0.0)	25	0 (0.0)	—	—	—
HBV vaccination policy	Tertiary	4	1 (25.0)	2	0 (0.0)	2.143	0.059–77.605	1.000
	Secondary	14	5 (35.7)	22	2 (9.1)	5.556	0.901–34.261	0.084
	Primary	13	0 (0.0)	25	0 (0.0)	—	—	—
Biosafety manual	Tertiary	4	1 (25.0)	2	0 (0.0)	2.143	0.059–77.605	1.000
	Secondary	14	0 (0.0)	22	0 (0.0)	—	—	—
	Primary	13	0 (0.0)	25	0 (0.0)	—	—	—
Biohazard sign	Tertiary	4	1 (25.0)	2	0 (0.0)	2.143	0.059–77.605	1.000
	Secondary	14	2 (14.3)	22	0 (0.0)	9.000	0.399–202.77	0.144
	Primary	13	0 (0.0)	25	0 (0.0)	—	—	—

CI, confidence interval; N₁, number of public laboratories; N₂ number of private laboratories; OR, odds ratio; SOP, standard operating procedure.

making relating to the allocation of resources in promoting safety in the work area. A biohazard sign on a laboratory entrance was observed in 3.75% of all laboratories surveyed. This is far lower than the reported value of 43.5% in a study conducted in Thailand [18].

None of the laboratories in the private sector had written SOPs for tests carried out. The situation was nonetheless better in the public sector, where only five (16.1%) of the laboratories surveyed had a written set of SOPs for tests. This value is lower than the 23.7% previously reported in another African study [12]. A documented SOP is critical in ensuring the consistency of test performance and results [9]. Writing SOPs and asking laboratory staff to follow these rules comprise a complete strategy for increasing and sustaining safe laboratory behavior [19]. The biosafety officer is expected to constantly provide this information, involve staff in the development and adherence to the final SOPs, and ensure that resources are made available to comply with them [19]. In this study, no biosafety officer was found in all laboratories surveyed, and this may account for many of the administrative lapses on biosafety issues observed. There is an urgent need, judging from the findings of this study, for the appointment of qualified and certified persons as biosafety officers.

It is important to note that the questionnaires were filled out by heads/owners of the laboratories and not by hands-on staff. Therefore, the data presented may not represent the true picture, and we opine that the actual situation may be worse. This is the limitation to this study.

Generally, among laboratories examined, very poor compliance rate was observed in issues relating to facility design, presence of personal protective barriers, equipment, and administrative control of biosafety. This was observed to reduce generally from tertiary to primary diagnostic laboratories. Undoubtedly, there is a need for increased investment in the provision of adequate personal protective equipment and adequate architectural structural design for laboratories in Nigeria. Findings from this study may therefore be used as baseline data by international agencies and nongovernmental organization in strengthening the capacity of laboratories in Nigeria for better service delivery. Laboratory managers and staff should also be constantly engaged in training on biosafety issues to increase their competency in dealing safely with infectious materials in the laboratory.

Conflict of interest

No conflict of interest exist in this work.

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